

K093228

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew TWINFIX Ultra PK Suture Anchor

Date Prepared: October 14, 2009

A. Submitter's Name:

DEC 15 2009

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover MA, 01810

B. Company Contact

Christina Flores
Regulatory Affairs Specialist II
Phone: (508) 261-3705
FAX: (508) 261-3620

C. Device Name

Trade Name: TWINFIX Ultra PK Suture Anchor
Common Name: Suture Anchor
Classification Name: Fastener, fixation, non-degradable, soft tissue

D. Predicate Devices

The Smith & Nephew TWINFIX Ultra PK Anchor is substantially equivalent in Intended Use and fundamental scientific technology to the legally marketed Smith & Nephew TWINFIX PK FT Suture Anchor cleared via K072875.

E. Description of Device

The TWINFIX Ultra PK is a suture anchor manufactured from PEEK (polyetheretherketone) and is offered in diameters of 4.5, 5.5, and 6.5 mm sizes. The screw-in anchor is preloaded with ultra high molecular weight polyethylene suture preassembled onto a stainless steel inserter.

F. Intended Use

The Smith & Nephew TWINFIX Ultra PK Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder:

Bankart lesion repairs
Slap lesion repairs
Capsular shift or capsulolabral reconstructions
Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Foot/Ankle:

Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions

Knee:

Extra-capsular repairs:
Medial collateral ligament
Lateral collateral ligament
Posterior oblique ligament
Patellar realignment and tendon repairs:
Vastus medialis obliquous advancement
Illiotalband tenodesis.

Elbow:

Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair
Biceps tendon reattachment
Metatarsal ligament/tendon repairs/reconstruction
Midfoot reconstructions

G. Comparison of Technological Characteristics

Device Characteristics	TWINFIX FT PK Predicate Device	TWINFIX Ultra PK Proposed Device
Device Design/Principles of Operation	Tap-in/Screw-in anchor	Screw-in suture anchor
Materials	PEEK with polyethylene suture	PEEK with polyethylene suture

Sterilization Method	EO	EO
Intended Use	Attachment of soft tissue to bone	Attachment of soft tissue to bone
Indications for Use	Reattachment of soft tissue to bone in Shoulder: Bankart lesion repairs Slap lesion repairs Capsular shift or capsulolabral reconstructions Acromioclavicular separation repairs Deltoid repairs Rotator cuff tear repairs Biceps tenodesis Foot/Ankle: Hallux valgus repairs Medial or lateral instability repairs/reconstructions Achilles tendon repairs/reconstructions Midfoot reconstructions Metatarsal ligament/tendon repairs/reconstruction Knee: Extra-capsular repairs: Medial collateral ligament Lateral collateral ligament Posterior oblique ligament Patellar realignment and tendon repairs: Vastus medialis obliquous advancement Illiobtibial band tenodesis. Elbow: Ulnar or radial collateral ligament reconstructions Lateral epicondylitis repair Biceps tendon reattachment	Reattachment of soft tissue to bone in Shoulder: Bankart lesion repairs Slap lesion repairs Capsular shift or capsulolabral reconstructions Acromioclavicular separation repairs Deltoid repairs Rotator cuff tear repairs Biceps tenodesis Foot/Ankle: Hallux valgus repairs Medial or lateral instability repairs/reconstructions Achilles tendon repairs/reconstructions Midfoot reconstructions Metatarsal ligament/tendon repairs/reconstruction Knee: Extra-capsular repairs: Medial collateral ligament Lateral collateral ligament Posterior oblique ligament Patellar realignment and tendon repairs: Vastus medialis obliquous advancement Illiobtibial band tenodesis. Elbow: Ulnar or radial collateral ligament reconstructions Lateral epicondylitis repair Biceps tendon reattachment

H. Summary Performance Data

The performance testing conducted demonstrates that the insertion and fixation properties of the Smith & Nephew TWINFIX Ultra PK suture anchor is substantially equivalent to the predicate TWINFIX FT PK suture anchor, cleared via K072875. The testing also demonstrates that the differences in the new device and the predicate device do not raise any new issues of safety and efficacy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Smith & Nephew Inc., Endoscopy Division
% Ms. Christina Flores
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

DEC 15 2009

Re: K093228
Trade/Device Name: Smith & Nephew TWINFIX Ultra PK Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded bone fixation fasteners
Regulatory Class: Class II
Product Code: MBI
Dated: October 14, 2009
Received: October 15, 2009

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use510(k) Number (if known): K093228Device Name: Smith & Nephew TWINFIX Ultra PK Suture Anchor**Indications For Use:**

The Smith & Nephew TWINFIX Ultra PK Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications:

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Knee:

Extra-capsular repairs:
 Medial collateral ligament
 Lateral collateral ligament
 Posterior oblique ligament
 Patellar realignment and tendon repairs:
 Vastus medialis obliquous advancement
 Illiotibial band tenodesis.

Foot & Ankle:

Hallux valgus repairs
 Medial or lateral instability repairs/reconstructions
 Achilles tendon repairs/reconstruction
 Midfoot reconstructions
 Metatarsal ligament/tendon repairs/reconstructions

Elbow:

Ulnar or radial collateral ligament reconstructions
 Lateral epicondylitis repair
 Biceps tendon reattachment

Prescription Use x

AND/OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Smith J for Concurrence of CDRH, Office of Device Evaluation (ODE)
 (Division Sign-Off) MM
 Division of Surgical, Orthopedic,
 and Restorative Devices

510(k) Number K093228